REMARKS & ARGUMENTS

Claims 1-14 and 46-57 are pending.

No amendments to the claims are being made and a listing of claims is thus not included in this paper.

35 U.S.C § 112, first paragraph

The Office objected to the specification and rejected claims 1-15 and 46-53 as allegedly not enabled. Applicants respectfully traverse the rejection.

To establish and maintain a rejection under 35 U.S.C. §112, first paragraph, the Office must provide logical reasoning to support its position. The Office must "explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi and Horton*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). The Office must advance "substantive reasons why the instant specification is non-enabling." "Mere broad generalizations and allegations are insufficient for holding of non-enablement." *Ex parte Goeddel* 5 U.S.P.Q. 2d 1449 (B.P.A.I. 1987). The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. *In Re Vaeck* 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991), *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.* 224 U.S.P.Q. 409 (Fed. Cir. 1984). It is irrelevant whether objective enablement is based on working examples or on broad terminology. *In Re Vaeck*, supra, *Atlas Powder Co.*, supra. To meet the requirement under the first paragraph of § 112, the specification, when filed, must enable one skilled in the particular art to use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988), *Ex parte Forman* 230 U.S.P.Q. 546 (B.P.A.I. 1986). In addition, even if some of the claimed embodiments were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ." *Atlas Powder Co.*, supra, *In re Dinh-Nguyen*, 492 F.2d 856 (C.C.P.A. 1974).

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *In re Wands, supra*. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Ex parte Jackson, et al.*, 217 U.S.P.Q. 804 (B. P. A. I. 1982), *In re Ranier, et al.,* 146 U.S.P.Q. 218 (C.C.P.A. 1965). As explained below, Applicant respectfully submits that the specification enabled the claimed subject matter.

In casting the rejection, the Office stated: "Claims that recite an optionally substituted alkyl group or alkenyl group or alkynyl or aryl moiety for example without describing the substituent are considered very broad. There are numerous possible substituents. While a species has been elected, the claims are not so limited. . . . . The specification and examples shows different compounds matched with particular disorders however there is no evidence of a single compound having an effect on any blood cell disorder." Applicants respectfully traverse these statements and request consideration of all of the references that Applicants have submitted in their information disclosure statements. The Office has apparently overlooked the fact that claims 53, 54, 56 and 57 recite a single compound that does not contain any substituted or unsubstituted group, including any alkyl, alkenyl, alkynyl or aryl group. And, since the Office has not considered the Stickney et al reference (40th Annual Meeting of the American Society of Clinical Oncology, Annual Meeting Proceedings vol. 23, abstract 6668, 2004, cited June 23, 2004, not considered by the Office) that Applicants submitted in their response to the prior office action, the Office's rationale is not based on a reasoned analysis of all relevant information.

The data in the Stickney et al publication shows that the compound recited in claims 53, 54, 56 and 57 has activity in treating both neutropenia and thrombocytopenia that is associated with either chemotherapy or radiation

exposure. The methods described in that publication closely mirror the methods contained in the present specification. Applicants have thus presented objective evidence that a compound within the scope of the claims has activity. As noted above, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Ex parte Jackson, supra.* In view of the foregoing, Applicants respectfully submit that the specification, including its detailed teaching enabled the claims. In view of this, the Office cannot base an enablement rejection on a fair evaluation of all evidence.

Applicants direct the Office's attention to the teaching in the application, including (1) example 38 beginning at paragraph 1270, which provides detailed protocols for modulating hematopoiesis, (2) examples 39 and 40 beginning at paragraphs 1283 and 1293, which provide detailed human clinical protocols for use of compounds within the scope of the claims, (3) the specification beginning at paragraph 602, which provides detailed discussion of methods to make, prepare and use formulations that contain the compounds, and (4) the specification beginning at paragraph 602, which provides detailed discussion of treatments for blood cell deficiencies. The specification thus provides a reasonable amount of guidance with respect to the direction in which experimentation would proceed. Any such experimentation is permissible, since it would be merely routine. Applicants respectfully request that the Office take into account the extensive and detailed teaching the specification contains. Applicants submit that in view of this teaching and the evidence of efficacy, one of ordinary skill in the art could practice the claimed invention without undue experimentation.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants' representative can be reached at the number given below if the Office has any questions or would like to address any other matters that may arise.

Respectfully submitted,

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